



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/599,292

09/25/2006

Adam Liebert

03100324 AA

6589

30743

7590

01/22/2009

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.

11491 SUNSET HILLS ROAD

SUITE 340

RESTON, VA 20190

EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,292	Applicant(s) LIEBERT ET AL.	
	Examiner VANI GUPTA	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/25/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is

Art Unit: 3768

separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Objections to Content of Specification

The disclosure is objected to because of the following informalities: while the specification provides the necessary and/or required sections as expressed above, the sections themselves are not clearly separated or defined with their corresponding headings. The following sections should be labeled along the lines of:

- 1) background of the invention: “Background of the Invention;”
- 2) summary of the invention: “Summary of the Invention;”
- 3) brief summary of the figures: “Brief Description;” and
- 4) detailed description of invention: “Detailed Description of the Invention.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. ***Claims 1 – 3, 5, 6, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

Regarding Claim 1, line 5, the subject matter in question is “temporal relation.”

Although the specification of the present invention (page 6, lines 26 – 28) describes that “the measurement of the temporal relation or for the time profile of the fluorescence response can also be carried out using high-frequency modulated light...,” it does not provide a clear definition of what “temporal relation” is.

Art Unit: 3768

Regarding Claim 3, line 2, the subject matter in question is “time profile.” Please refer to the aforementioned rejection of Claim 1 for explanation.

Claim 1 is also rejected for being vague and indefinite because it does not provide the proper transitional phrase. The claim language of the preamble should read along the lines of, “A method for...., comprising the steps.” Appropriate correction is required.

Regarding Claim 2, line 2, the subject matter in question is “short pulse.” The claim language of this claim is vague and indefinite because it does not specify “short.” Although the specification of the present invention (page 3, lines 24 – 25; and page 7, lines 34 – 35) refers to “short laser pulses,” Examiner respectfully reminds Applicant that during examination, although the claims are read in light of the specification, the specification never limits the features of the claims.

Claim 5 is rejected for being vague and indefinite because the specification does not provide a clear indication of how one may detect the reflected excitation radiation simultaneously and in parallel.

Claim 6 is rejected for being vague and indefinite because the specification does not provide a clear indication of how one may detect the reflected excitation radiation with time resolution. Additionally, since this claim is dependent on Claim 5, neither the specification nor the claim language of either claims provide how one may carry out the detection of the reflected excitation radiation with time resolution in the context of detecting the radiation “simultaneously and in parallel.”

Claim 11 is rejected for being vague and indefinite because it does not provide the proper transitional phrase. The claim language of the preamble should read along the lines of, “A system for...., comprising.” Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. *Claim 1 – 3, 5 – 8, 11 – 13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Flower (US 7, 364,574 B2).*

Regarding Claims 1(a) and 1(b), Flower discloses a method for detecting a dye bolus injected into the body of a living being, by irradiating optical radiation into the body and detecting a response radiation occurring on the surface of the body, characterized in that

(a) a fluorescent dye (is injected (col. 3, lines 58 – 64; and col. 4, lines 20 – 24); and

(b) an optical excitation radiation is irradiated into the body (col. 3, line 64 – col. 4, line 4; and col. 4, lines 24 – 27).

With respect to Claim 1(c), 7, and 8, Applicant should note that for the purposes of examination, and in light of the aforementioned 35 U.S.C. 112 second paragraph rejection, Examiner interprets that “measuring temporal relation between a fluorescent radiation and excitation radiation” refers to detecting the location of the dye bolus within the body based on the location of the fluorescence from the fluorescing agent, such as ICG.

Art Unit: 3768

Flower's method and system includes capturing images of the fluorescing vasculature as high speed angiographic images (col. 2, lines 41 – 45; col. 5, lines 61 – 65). These images then are analyzed to identify a lesion and blood vessels associated with that lesion (col. 1, line 58 – col. 2, line 12; and col. 5, line – 61 – col. 6, line 15).

Regarding Claim 2, Flower's excitation radiation is emitted as a short pulse (col. 4, lines 39 – 47).

With respect to Claim 3, Examiner interprets "time profile" to mean the amount of time the fluorescing dye is present in the ROI (col. 6, lines 4 – 15).

With respect with claims 5 and 6, Examiner interprets the claim limitations to mean that as radiation is applied, one can monitor the PDT agent and its affect on a ROI and therefore control the amount of radiation applied. Fluorescing agent may be applied simultaneously with the PDT agent to assist in the monitoring (*col. 5, line 61 – col. 6, line 63*).

With regard to Claim 11, Flower discloses a device (**fig. 2, 200**) for detecting a dye bolus injected into the body of a living being, with an optical radiation source (**228, 229, 230**) for irradiating an optical radiation into the body, and a detection arrangement (**220**) for detecting a response radiation emanating from the body (col. 8, lines 6 – 50).

With reference to the limitation: "the optical radiation source is designed to emit an excitation radiation with a first frequency, and the detection arrangement is designed to detect a response radiation with a second frequency different than the first frequency and to determine a temporal relation between the emitted excitation radiation and at least part of the detected response radiation," this is a property that is inherent to all medical systems, in that when an energy is applied to an object such an internal organ of a patient, the resultant or detected energy

Art Unit: 3768

will be at a different frequency because of the inhomogenous properties of the organs that alter the frequency of the applied energy.

Regarding Claim 12, please see column 4, lines 40 - 47.

Regarding Claim 13, Flower's detection system is capable of detecting a time profile of the fluorescent radiation triggered by a pulse of the excitation radiation (please refer to aforementioned rejections for support).

Regarding Claim 16, Flower discloses an evaluation unit for evaluating temporal changes of the measured temporal relation (*processor*, 222).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3768

4. *Claim 4 and 14 are rejected under 35 USC 103(a) as being obvious over Flower (US 7,364,574 B2) in view of Schlier et al. (US 5,400,791).*

Regarding claims 4 and 14, Flower discloses a method and system for detecting a dye bolus, as explained above.

Flower differs from these claims in that he does not appear to specifically disclose an optical filter for blocking off the frequency of the excitation radiation.

However, Schlier teaches an optical filter “having a sharp cut-off response matched to the excitation and emission peaks of a fluorescing dye (*Abstract*).

Accordingly, Schlier complements the disclosing of Flower by teaching an optical filter that increases the sensitivity of the detection of the dye bolus (*col. 5, line 40 – 55*).

Therefore, it would have been prima facie obvious to modify Flower with the teachings of Schlier to include an optical filter to obtain the invention in the instant claims 4 and 14.

5. *Claims 9, 10, and 15 are rejected under 35 USC 103(a) as being obvious over Flower (US 7,364,574 B2).*

Regarding claims 9 and 10, Flower discloses that excitation radiation is irradiated into the body in the areas of the eye (**Background of the Invention**).

Flowers differs from claims 9 and 10 in that he does not appear to specifically disclose that excitation radiation is irradiated into the body at the head in order to examine the brain, or irradiated into the body in the area of the lungs .

However, Flower does discuss that excitation irradiation is irradiated into the body at the head in order to examine the eye. Since the eyes are near the head, it would be obvious to one of ordinary skill in the art, that Flower's method could entail applying the excitation irradiation to

Art Unit: 3768

the brain as well. Flower also discusses applying the bolus to the thoracic cavity for his radiation treatment (*col. 5, lines 55 – 60*).

Furthermore as Flowers explains, and would be obvious to one of ordinary skill in the art, photodynamic therapy is used to treat areas of the body where blood flows, such as the eyes, brain, lungs, etc (Summary of the Invention). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify Flowers to include a step of irradiating areas of the body such as the head or lungs for assessing perfusion to obtain the invention in the instant claims 9 and 10.

Regarding Claim 15, Applicant should note that providing an additional detector branch for detection of reflected excitation radiation is an obvious matter of design choice, wherein no stated problem is solved or unexpected result obtained in having the arrangement taught by Flower, and since rearrangement parts of a device involves only routine skill in the art.

See *In re Japikse*, 86 USPQ 70.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Hochman et al. (US 6,161,031)* for imaging changes in electromagnetic absorption which reflects dynamics of dye perfusion through tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

Art Unit: 3768

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768